DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 23, 2014

Karl Storz Endoscopy-America, Inc.
Mike Samuels
Regulatory Affairs Specialist
2151 E. Grand Avenue
El Segundo, CA 90245

Re: K142556
Trade/Device Name: Flexible Video-Uretero-Choledochoscope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Codes: FGB, FBN
Dated: September 10, 2014
Received: September 11, 2014

Dear Mike Samuels,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142556

Device Name
Flexible Video-Uretero-Choledochoscope System

Indications for Use *(Describe)*
The KARL STORZ Flexible Video-Uretero- Choledochoscope System is indicated for endoscopic examination in the urinary tract and can be used percutaneously to examine the interior of the kidney, and using additional accessories, to perform various diagnostic and therapeutic procedures. The Flexible Video-Uretero-Choledochoscope System is also indicated for the examination of bile ducts, and using additional accessories, to perform various diagnostic and therapeutic procedures during cholecystectomy.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant:	Karl Storz Endoscopy-America, Inc 2151 E. Grand Avenue El Segundo, CA 90245
Contact:	Mike Samuels Regulatory Affairs Specialist Phone: (424) 218-8288 Fax: (424) 218-8519
Date of Preparation:	September 10, 2014
Device Identification:	Trade Name: Flexible Choledochoscope Common Name: Flexible Video-Uretero-Choledochoscope System Classification Name: Choledochoscope and Accessories, Flexible/ Rigid
Product Code:	FGB and FBN
Regulation:	21 CFR part 876.1500
Predicate Device(s):	The primary predicate device is the DUR-Digital Ureteroscope and Choledochoscope System (DUR®-D), K060269, manufactured by ACMI Corporation. The secondary predicate is the KARL STORZ Flexible Video-Uretero-Renoscope System, K141250.
Device Description:	The Flexible Video-Uretero-Choledochoscope System is used for visualization purposes during diagnostic and therapeutic procedures. The system components are the Flexible Video-Uretero-Choledochoscope and the Image 1 SPIES Camera Control Unit (CCU). The Flexible Video-Uretero-Choledochoscope uses an LED light integrated in the handle and fiber light guides to illuminate the cavity under examination. The video image is produced by a complementary metal–oxide–semiconductor (CMOS) imaging sensor located at the tip of the insertion shaft. The imaging sensor transfers the video signal to the Image 1

	SPIES CCU via electronics in the handle. The Image1 HD CCU processes the sensor images and displays them on a standard HD display monitor. This change is to expand the indications for the currently cleared secondary predicate Flexible Video-Uretero-Renoscope System (K141250) to allow it to also be marketed as a Choledochoscope used for examination of the bile duct and to allow the ability to percutaneously access the abdominal cavity for examination of the kidney. No changes were made to the device design as part of this update. Only the model number and applicable labeling were updated.
Indications For Use:	The Flexible Video-Uretero-Choledochoscope System is indicated for endoscopic examination in the urinary tract and can be used percutaneously to examine the interior of the kidney, and using additional accessories, to perform various diagnostic and therapeutic procedures. The Flexible Video-Uretero-Choledochoscope System is also indicated for the examination of bile ducts, and using additional accessories, to perform various diagnostic and therapeutic procedures during cholecystectomy.
Technological Characteristics:	The Karl Storz Flexible Video-Uretero-Choledochoscope System has the same indications for use as the originally cleared primary predicate ACMI Corporation DUR-Digital Ureteroscope and Choledochoscope System (DUR®-D), K06026. The Flexible Video-Uretero-Choledochoscope System and the secondary predicate Flexible Video-Uretero-Renoscope System (K141250), both manufactured by KARL STORZ, are exactly the same and share the same fundamental technology and physical characteristics. The methods of operation, design and materials used are either identical or substantially equivalent to existing legally marketed predicate devices.
Non-Clinical Performance Data:	The Flexible Video-Uretero-Choledchoscope System and the secondary predicate Flexible Video-Uretero-Renoscope System (K141250), both manufactured by KARL STORZ, are exactly the same and share the same fundamental technology and physical characteristics. Therefore, the performance data described in the cleared Flexible Video-Uretero-Renoscope System, K141250, is also applicable to the Flexible Video-Uretero-Choledochoscope System. No changes were made to the device design as part of this update. Only the model number and applicable labeling were updated. The KARL STORZ secondary predicate Flexible Video-Uretero-Renoscope System has been evaluated according to ISO 14971 risk management process and the system was successfully tested for its functions and

	performance; including verification of optical characteristics per ISO 8600 (image quality, illumination). Safety testing was performed including electrical safety IEC 60601-1, electromagnetic compatibility per IEC 60601-1-2, and biocompatibility of the patient contacting materials per ISO 10993. Additional validations were conducted for the manual cleaning method, sterilization process.
Clinical Performance Data:	Clinical testing was not required to demonstrate substantial equivalence to the predicate devices.
Conclusion:	The Flexible Video-Uretero-Choledochoscope System is substantially equivalent to its predicate devices. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as or better than the legally marketed devices.